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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,662	10/10/2006	Patrick Gerard Johnston	36290-0416-00-US	5029

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EXAMINER

NATARAJAN, MEERA

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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03/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,662	Applicant(s) JOHNSTON ET AL.	
	Examiner MEERA NATARAJAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 14, 16-20, 23, 25-28, 31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 23, 25-28, 31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/09/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments in the reply filed on 12/09/2008 is acknowledged and entered into the record.
2. Accordingly, Claims 9-11, 14, 16-20, 23, 25-28, 31, 33, and 34 are pending.
3. Claims 9-11, 14, 16 and 17 are withdrawn as being drawn to non-elected inventions.
4. Claims 18-20, 23, 25-28, 31, 33 and 34 will be examined on the merits.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18, 19, 20, 23, 27, 28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al. (Oncogene, Vol. 20, pp.1852-1859, 2001).
7. The Claims are drawn to a product or pharmaceutical composition comprising the anti-FAS antibody, CH11, and a topoisomerase 1 inhibitor chemotherapeutic agent.

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8. Shao et al. teach the treatment of cells with the anti-FAS antibody CH-11 and the topoisomerase 1 inhibitor, camptothecin (CPT) (see figure 8A on p.1856). Applicant is reminded that the intended use of a product claim carries no patentable weight [MPEP 2111.02].

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 18-20, 23, 25-28, 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shao et al. (Oncogene, Vol. 20, pp.1852-1859, 2001) in view of Ulukan et al. (Drugs, Vol. 62(14), pp.2039-2057, 2002).

12. The Claims are drawn to a product or pharmaceutical composition comprising the anti-FAS antibody, CH11, and a topoisomerase 1 inhibitor chemotherapeutic agent, irinotecan (CPT-11).

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13. The teachings of Shao et al. are presented in the 102(b) rejection set forth above. Shao et al. does not teach the topoisomerase 1 inhibitor, irinotecan. This deficiency is made up for by Ulukan et al.

14. Ulukan et al. teach camptothecins and their antitumour activity by binding to topoisomerase 1 and have shown significant activity against a broad range of tumors. Camptothecins analogues and derivatives have been used in cancer therapy because of manageable toxicity and encouraging activity against solid tumours and offer promise in the clinical management of human tumours.

15. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the camptothecin derivative, irinotecan, as taught by Ulukan et al. in combination with the anti-FAS antibody CH-11 as taught by Shao et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Ulukan et al. that camptothecin analogues and derivatives can be used for cancer therapy. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

Double Patenting Rejection Maintained

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude”

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granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. The rejection of Claims 18-20, 23, 25, 27, 28, 31, and 33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 19, 23, 24, 26, 30, 31 and 33 of copending Application No. 10/514604 is maintained for the reasons of record. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicants' indicated in the response filed 12/09/2008 that "applicants defer response, as the rejection is provisional in nature because the allegedly conflicting claims have not been patented and applicants reserve the right to respond to the rejection should the allegedly conflicting claims become patented." Applicants response is considered "non-responsive" since Applicant did not point out the supposed errors in the rejection. The provisional obviousness-type double patenting rejection is therefore maintained.

***All previous rejections are withdrawn in view of applicants
amendments/arguments in the response filed 12/09/2008.***

Conclusion

18. Claims 18-20, 23, 25-28, 31, 33 and 34 are rejected.
19. No Claim is allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

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Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643